Policy Number	**THE803.021**
Policy Effective Date	**12/15/2024**

Vertebral Axial Decompression

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Vertebral axial decompression traction device for the treatment of neck or back pain in any setting (e.g., home, office, rehabilitation clinic) **is considered experimental, investigational and/or unproven.**

Policy Guidelines

CPT Code 97012 should not be used to describe vertebral axial decompression; there is a specific HCPCS S-code, S9090 for vertebral axial decompression.

Description

Vertebral axial decompression applies traction to the vertebral column to reduce intradiscal pressure and, in doing so, potentially relieves low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

Background

Vertebral axial decompression (also referred to as mechanized spinal distraction therapy) is used as traction therapy to treat chronic low back pain. Specific devices available are described in the Regulatory Status section.

In general, during treatment, the patient wears a pelvic harness and lies prone on a specially equipped table. The table is slowly extended, and a distraction force is applied via the pelvic harness until the desired tension is reached, followed by a gradual decrease of the tension. The cyclic nature of the treatment allows the patient to withstand stronger distraction forces compared with static lumbar traction techniques. An individual session typically includes 15 cycles of tension, and 10 to 15 daily treatments may be administered.

Regulatory Status

Several devices used for vertebral axial decompression have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of these devices include the VAX-D®, Decompression Reduction Stabilization (DRS®) System, Accu-SPINA® System, DRX-3000®, DRX9000®, SpineMED Decompression Table®, Antalgic-Trak®, Lordex® Traction Unit, and Triton® DTS. According to labeled indications from the FDA, vertebral axial decompression may be used as a treatment modality for patients with incapacitating low back pain and for decompression of the intervertebral discs and facet joints.

FDA product code: ITH.

Rationale

Medical policies Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice

Vertebral Axial Decompression for Chronic Lumbar Pain

Clinical Context and Therapy Purpose

The purpose of vertebral axial decompression is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with chronic lumbar pain due to disc-related causes.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with chronic lumbar pain due to disc-related causes.

Interventions

The therapy being considered is vertebral axial decompression.

Vertebral axial decompression applies traction to the vertebral column to reduce intradiscal pressure, and in doing so, potentially relieves low back pain associated with herniated lumbar discs or degenerative lumbar disc disease.

Comparators

The following practice is currently being used to treat chronic lumbar pain due to disc-related causes: standard conservative therapy.

Conservative management includes nonsteroidal anti-inflammatory medications, back braces, and physical therapy; other nonsurgical treatments could include muscle relaxants, narcotic pain medications, or epidural steroid injections. (1)

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Follow-up for patients receiving vertebral axial decompression would ideally be 6 months or longer.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Vanti et al. (2021) published a systematic review with meta-analysis that evaluated the efficacy of mechanical traction with or without other conservative treatments on pain and disability in adults with lumbar radiculopathy. (2) A list of studies included in the meta-analysis is found in Table 1. The characteristics of trials included in the systematic review and results of the meta-analysis are summarized in Tables 2 and 3, respectively. Of note, only analyses that included more than 1 RCT are summarized in Table 3. Briefly, results demonstrated that supine mechanical traction added to physical therapy had significant effects on pain and disability, whereas, prone mechanical traction added to physical therapy did not demonstrate these effects.

Wang et al. (2022) published a meta-analysis evaluating the efficacy of mechanical traction for pain associated with lumbar disc herniation. (3) Six RCTs (N=239) were included in analysis (Table 1). Characteristics of the review and results are listed in Tables 2 and 3, respectively. Overall, results demonstrated that mechanical traction was significantly better than conventional physical therapy in improving pain scores and disability scores. Heterogeneity was low among studies. The results are limited by relatively small sample sizes, short-term follow-up, and no standardized control groups among studies.

Table 1. Summary of Trials/Studies Included in SR & M-A

Study	Vanti et al. (2021) (2)	Wang et al. (2022) (3)
Al Amer et al. (2019)	•	
Bilgilisory Filiz et al. (2018)	•	•
Demirel et al. (2017)		•
Fritz et al. (2007)	•	
Isner-Horobeti et al. (2016)		•
Kotb et al. (2017)	•	
Moustafa and Diab (2013)		•
Ozturk et al. (2006)	•	•
Prasad et al. (2012)		•
Sherry et al. (2001)	•	
Thackeray et al. (2016)	•	
Unlu et al. (2008)	•	

M-A: meta-analysis; SR: systematic review.

Table 2. SR & M-A Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration

Vanti et al. (2021) (2)	1998 to 2019	8	Adults with lumbar radiculopathy using mechanical traction.	567 (44 to 120)	RCTs	Up to 3 months post-intervention
Wang et al. (2022) (3)	Searched through 2022	6	Adults with lumbar disc herniation receiving traction therapy combined with routine physical therapy.	239 (19 to 79)	RCTs	NR

M-A: meta-analysis; NR: not reported; RCT: randomized controlled trial; SR: systematic review.

Table 3. SR & M-A Results

Study	**Pain (change in VAS)**	**Disability (ODI or RMDQ)**
Vanti et al. (2021) (2)		
Mechanical traction in *prone* position plus physical therapy vs. physical therapy		
N	263	263
Pooled effect (95% CI)	-0.29 (-0.58 to 0.01)	-0.10 (-0.34 to 0.14)
p value	.05	.43
Mechanical traction in *supine* position plus physical therapy vs. physical therapy		
N	185	139
Pooled effect (95% CI)	-0.58 (-0.87 to -0.29)	-0.78 (-1.45 to -0.11)
p value	.00	.02
Wang et al. (2022) (3)	**Pain (change in VAS)**	**Disability (ODI)**
Mechanical traction vs. conventional physical therapy		
N	239	222
MD (95% CI)	-1.39 (-1.81 to -0.98)	-6.34 (-10.28 to -2.39)
p value	<.00001	.002

CI: confidence interval; M-A: meta-analysis; MD: mean difference; ODI: Oswestry Disability Index; RMDQ: Roland & Morris Disability Questionnaire; SR: systematic review; VAS: visual analog scale.

Randomized Controlled Trials (RCTs)

Results from RCTs not included in the systematic reviews are as follows. Key characteristics and results from these RCTs are summarized in Tables 4 and 5, respectively.

Schimmel et al. (2009) published results from a randomized sham-controlled trial of intervertebral axial decompression. (4) Sixty subjects with chronic symptomatic lumbar disc degeneration or bulging disc with no radicular pain and no prior surgical treatment (dynamic stabilization, fusion, or disc replacement) were randomized to a graded activity program with an Accu-SPINA device (20 traction sessions during 6 weeks, reaching >50% of body weight) or to

a graded activity program with a non-therapeutic level of traction (<10% body weight). In addition to traction, the device provided massage, heat, relaxing blue light, and music during the treatment sessions. While the physiotherapist who conducted the lumbar traction was unblinded, neither patients nor evaluators were informed about the intervention received until after the 14-week follow-up assessment and the intention-to-treat analysis was performed (93% of subjects completed follow-up). Both groups showed improvements in validated outcome measures (visual analog scale scores for back and leg pain, Oswestry Disability Index, 36-Item Short-Form Health Survey) but there were no significant differences between treatment groups. For example, visual analog scale scores for low back pain (the primary outcome) decreased from 61 to 32 in the active group and from 53 to 36 in the sham group. Evidence from this RCT did not support improvements in health outcomes with vertebral axial decompression.

Table 4. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Schimmel et al. (2009) (4)	Netherlands	10	NR	N=60 patients with chronic symptomatic lumbar disc degeneration or bulging disc with no radicular pain and no prior surgical treatment	Graded activity program with an Accu-SPINA device (>50% of body weight; n=31)	Graded activity program with a non-therapeutic level of traction (<10% body weight; n=29)

NR: not reported; RCT: randomized controlled trial.

Table 5. Summary of Key RCT Results

Study	VAS score
Schimmel et al. (2009) (4)	
	Week 14
Accu-SPINA device, n	30
Mean (SD)	32 (± 26.8)
Sham traction, n	26
Mean (SD)	36 (± 27.1)
p value (between-group)	.695

CI: confidence interval; MD: mean difference; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analogue scale.

The purpose of the study limitations tables (see Tables 6 and 7) is to display notable limitations identified in each study.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow up[e]
Schimmel et al. (2009) (4)					1. Not sufficient duration for benefit (14 weeks)

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Complete-ness[d]	Power[e]	Statistical[f]
Schimmel et al. (2009) (4)		4. Physio-therapist who conducted the lumbar traction was unblinded			4. Power not met	

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Summary of Evidence

For individuals with chronic lumbar pain who receive vertebral axial decompression, the evidence includes 2 systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Evidence for the efficacy of vertebral axial decompression on health outcomes is limited. Because a placebo effect may be expected with any treatment that has pain relief as the principal outcome, RCTs with sham controls and validated outcome measures are required. The only sham-controlled randomized trial published to date did not show a benefit of vertebral axial decompression compared with the control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society published guidelines in 2020 on the treatment of low back pain. (5) Their recommendation related to lumbar traction is as follows: "In patients with subacute or chronic low back pain, traction is not recommended to provide clinically significant improvements in pain or function."

Ongoing and Unpublished Clinical Trials

An online search of www.ClinicalTrials.gov in February 2024 did not identify ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97012, 97530
HCPCS Codes	S9090

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

References

1. Peloza J. Non-surgical treatments for lower back pain. Spine-health. Updated April 20, 2017. Available at <https://www.spine-health.com> (accessed February 15, 2024).
2. Vanti, C, Turone L, Panizzolo A, et al. Vertical traction for lumbar radiculopathy: a systematic review. Arch Physiother. Mar 15 2021; 11(1):7. PMID 33715638

3. Wang W, Long F, Wu X, et al. Clinical Efficacy of Mechanical Traction as Physical Therapy for Lumbar Disc Herniation: A Meta-Analysis. Comput Math Methods Med. 2022; 2022:5670303. PMID 35774300
4. Schimmel JJ, de Kleuver M, Horsting PP, et al. No effect of traction in patients with low back pain: a single centre, single blind, randomized controlled trial of Intervertebral Differential Dynamics Therapy. Eur Spine J. Dec 2009; 18(12):1843-1850. PMID 19484433
5. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: diagnosis & treatment of low back pain. 2020. Available at <https://www.spine.org> (accessed February 15, 2024).
6. Centers for Medicare & Medicaid Services. National Coverage Decision (NCD) for Vertebral Axial Decompression (VAX-D) (160.16). 1997. Available at <https://www.cms.gov> (accessed February 15, 2024).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2024	Document updated with literature review. Coverage unchanged. Added references 3, 5, and 6; one removed.
12/01/2023	Reviewed. No changes.
02/01/2023	Document updated with literature review. The following change was made to Coverage: Modified coverage statement to be specific to vertebral axial decompression; content related to other types of non-surgical spinal decompression traction devices are already addressed in other policies (i.e., DME101.041, DME101.046). Added references 1 and 2; others removed. Title changed from Non-Surgical Spinal Decompression Traction Devices.
07/01/2021	Reviewed. No changes.
06/01/2020	Document updated with literature review. Coverage unchanged. Reference 11 added.
06/15/2018	Reviewed. No changes.
12/15/2017	Document updated with literature review. Coverage unchanged.
09/15/2016	Reviewed. No changes.

05/01/2015	Document updated with literature review. Coverage statement changed to include “neck” pain: The use of any non-surgical spinal decompression traction device for the treatment of neck or back pain in any setting (e.g., home, office, rehabilitation clinic) is considered experimental, investigational and/or unproven.
08/01/2013	Document updated with literature review. Coverage unchanged. Rationale and References reorganized.
05/01/2011	Document updated with literature review. No change in coverage.
05/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
08/15/2007	Revised/updated entire document
02/01/2007	Revised/updated entire document
10/15/2004	Revised/updated entire document
12/01/2003	Revised/updated entire document
01/01/2000	Revised/updated entire document
08/01/1999	New medical document